

Ecotox Report for Case # P-18-0137

General

<p>Status 09/21/2018 Date: SAT Date: 04/13/2018</p> <p>Consolidated N PMN: Ecotox [REDACTED] Related Cases: Health Related Cases: Submitter: Wacker Chemical Corporation CAS Number: [REDACTED] Chemical Name: [REDACTED] Use: Water repellent for fiber-reinforced cement products, like fiber-cement board. The PMN material significantly reduces the capillary water absorption of the construction materials after setting and reaching equilibrium moisture. [REDACTED] Trade Name: SILRES BS 1703 PV-max(kg/yr): [REDACTED]</p>	<p>Report Status: Complete CRSS Date: 04/12/2018</p> <p>SAT William Chair: Irwin Consolidated Set:</p> <p>Ecotox Gallagher, Assessor: Jeffrey</p>
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Fate Summary Statement

<p>Fate P-18-0137 Summary FATE: Statement: [REDACTED]</p>	<p>Liquid with MP < 25 °C (E) S = Reacts Hydrolysis half-life = hr-da VP < 1.0E-6 torr at 25 °C (E) BP > 400 °C (E) H < 1.00E-8 (E) POTW removal (%) = PMN 90 via hydrolysis; then Hyd Pdt 90 via sorption; Feedstock (CAS</p>
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Feedstock

NRB.

Time for complete ultimate aerobic biodeg = Hyd Pdt > mo

Sorption to soils/sediments = Hyd Pdt v.strong

PBT Potential: PMN

P1B1; Hyd Pdt P3B1

*CEB FATE: Migration to ground water = Hyd Pdt negl

PMN Material:

Overall wastewater treatment removal is 90%
via sorption and hydrolysis (hydrolysis half-life: hours to days).

Sorption to sludge is strong based on high molecular volume.

Air

Stripping (Volatilization to air) is negligible based on high molecular volume.

Removal by biodegradation in wastewater treatment is negligible based on measured data for an analog (Feedstock

and high molecular volume.

PMN Material:

Low Persistence (P1) is based on hydrolysis (hydrolysis half-life: hours to days).

Low Bioaccumulation potential (B1) is based on hydrolysis (hydrolysis half-life: hours to days).

Hydrolysis Product:

Overall wastewater treatment removal is 90% via sorption.

Sorption to sludge is strong based on high molecular volume.

Air Stripping (Volatilization to air) is negligible based on high molecular volume.

Removal by biodegradation in wastewater treatment is negligible based on measured data for an analog

NRB) and high molecular volume.

The aerobic aquatic biodegradation

half-life is greater than months based on measured data for an analog

and high molecular volume.

The anaerobic aquatic biodegradation

half-life is greater than months based on the aerobic biodegradation

half-life. The anaerobic biodegradation half-life is projected to be

greater or equal to the aerobic biodegradation half-life.

Sorption to soil and sediment is very strong

based on high molecular volume.

Migration to groundwater is

negligible based on high molecular volume and low estimated water solubility.

Hydrolysis Product:

High Persistence (P3) is based on

the aerobic and anaerobic biodegradation half-lives and high molecular volume.

Low Bioaccumulation potential (B1) is based on high molecular volume.

Bioconcentration/Bioaccumulation factor to be put into

E-Fast: N/A.

Physical

Chemical Information

Molecular Weight:		
Wt% < 500:		Wt% < 1000:
Physical State - Neat:	Liquid	
Melting Point:		Melting Point (est):
MP (EPI):		
Vapor Pressure:		Vapor Pressure (est):
VP (EPI):		
Water Solubility:		Water Solubility (est):
Water Solubility (EPI):		
Henry's Law::		
Log Koc:		

Log Kow:	Log Koc (EPI):
Log Kow (EPI):	
Log Kow Comment:	

SAT**Concern Level**

Ecotox 2
Rating (1):
Ecotox
Rating Comment
(1):
Ecotox Rating
(2):
Ecotox
Rating Comment
(2):
Ecotox Route of All releases to
Exposure: water

Ecotox Comments

Exposure Y
Based Review
(Eco):
Ecotox
Comments:
Exposure Based No
Testing:

PBT**Ratings**

Persistence	Bioaccumulation	Toxicity	Comments
1	1		PMN
3	1		Hyd Pdt

Eco-Toxicity Comment:**Fate Ratings**

Removal 90;90 in WWT/POTW PMN; Hyd Pdt (Overall):					Comment
Condition	Rating Values	1	2	Rating Description 3	
Fate Comments:	available.				

Ecotoxicity Values

Test organism	Test Type	Test Endpoint	Predicted	Experimental	Comments
Fish	96-h	LC50		41	Hydrolysis products of the monomer of the PMN
Daphnid	48-h	LC50		12	" "
Green Algae	96-h	EC50		>1.189	" "
Fish	-	Chronic Value		4.1	" "; ACR of 10
Daphnid	-	Chronic Value		1.2	" "; ACR of 10
Green Algae	-	Chronic Value		0.58	Hydrolysis products of the monomer of the PMN

Ecotox Value Predictions are based on measured data for

Comments:

[REDACTED] Log Kow
= 2.09; solid with a MP (P) of 72.3; S = 8.3 g/L (E); effective
concentrations based on 100% active ingredients and mean measured
concentrations; hardness <150 mg/L as CaCO₃; and TOC <2.0
mg/L

Ecotoxicity Test Data Results: P-18-0137; [REDACTED]

Test organism	Test Type	Test Endpoint	Predicted	Experimental Comments
				<p data-bbox="412 384 1421 1879"> Fish Ecotoxicity Test: IBACON GmbH conducted a 96-hour acute toxicity test in rainbow trout (<i>Oncorhynchus mykiss</i>) with a monomer of the PMN [REDACTED] under semi-static conditions with 24-hour renewal. The sponsor (Wacker Chemical Corporation) stated that, "It is reasonable to identify the monomer as a worst case structural surrogate for the notified polymer," P-18-0137. EPA agrees with this approach and notes that [REDACTED] hydrolyzes in approximately 40 hours to [REDACTED]. As a result, aquatic organisms will likely be exposed to [REDACTED] and its hydrolysis products during the test's exposure duration. The water solubility of the monomer [REDACTED] was reported to be < 0.25 mg/L. The water solubility of the hydrolysis products are 8.3 g/L (EpiSuite) for [REDACTED] and > 100 g/L (measured) for [REDACTED]. This study followed OECD test guideline No. 203 (1992) and Method C.1 of Directive 92/69/EEC (1992). Following a range-finding test, single replicates of seven <i>O. mykiss</i> were exposed to a dilution water control (reconstituted freshwater) or the test substance at nominal concentrations of 4.6, 10, 21, 46, or 100 mg/L. An additional replicate was exposed to a filtrate of a supersaturated stock suspension (100 mg/L) to determine the toxic effect of the dissolved part of the test item only. Analytical monitoring was not conducted as the laboratory was not able to establish a reproducible method to determine test item concentration. They tried Inductive Couples Plasma Emission Spectrometry (ICP-AES) and Atomic Absorption Spectroscopy (AAS) with a graphite furnace to detect the silicon. In the algal study below, Harlan laboratories used gas chromatography (GC) to detect the [REDACTED] without any problems. GC analysis might have been more appropriate for this new chemical submission. Nominal concentrations were prepared by directly weighing the test item into each aquarium and filling the chambers with test water. The content of the aquaria was stirred to dissolve the test item. The filtrate of the supersaturated stock suspension was prepared by ultrasonically treating a 100 mg/L solution for 15 minutes, followed by stirring for 24 hours to dissolve the highest possible rate of test item. The stock suspension was then filtered through a cellulose nitrate filter (pore size 0.45 µm). Over the course of the study, temperature ranged from 15-17°C, pH ranged from 6.7-7.9 and dissolved oxygen ranged from 7.1-9.8 mg/L. Dilution water hardness was 250 mg/L as CaCO₃. At concentrations ≤ 21 mg/L and in the filtrate, test media were clear with </p>

Test organism	Test Type	Test Endpoint	Predicted	Experimental Comments
				<p>no remarkable observations. At nominal test concentrations of 46 and 100 mg/L, a part of the test item was observed at the surface of the test water. A biomass loading rate of 0.79 g fish/L was calculated. The % mortality at 0 (control), 4.6, 10, 21, 46, and 100 mg/L was 0%, 0%, 0%, 29%, 43%, and 86%, respectively. The % mortality for the filtrate of a supersaturated stock suspension treatment was 43%. Sub-lethal effects included changed color (21, 46, and 100 mg/L, and filtrate), mucous secretion (46 and 100 mg/L), tumbling during swimming (21, 46 and 100 mg/L), and distended abdomen (100 mg/L). Based on nominal concentrations, the 96-hour LC50 was 41 mg/L. This is an acceptable test.</p> <p>96-hour LC₅₀ = 41 mg/L</p> <p>Invertebrate Ecotoxicity Test: IBACON GmbH conducted a 48-hour acute toxicity test in the water flea (<i>Daphnia magna</i>) with a monomer of the PMN ([REDACTED]) under semi-static conditions with 24-hour renewal. The sponsor (Wacker Chemical Corporation) stated that, "It is reasonable to identify the monomer as a worst case structural surrogate for the notified polymer," P-18-0137. EPA agrees with this approach and notes that [REDACTED] hydrolyzes in approximately 40 hours to [REDACTED] and [REDACTED]. As a result, aquatic organisms will likely be exposed to [REDACTED] and its hydrolysis products during the test's exposure duration. The water solubility of the monomer [REDACTED] was reported to be < 0.25 mg/L. The water solubility of the hydrolysis products are 8.3 g/L (EpiSuite) for [REDACTED] and > 100 g/L (measured) for [REDACTED]. This study followed OECD test guideline No. 202 (1984) and Method C.2 of Directive 92/69/EEC (1992). Following a range-finding test, two replicates of ten <i>D. magna</i> were exposed to a dilution water control (reconstituted freshwater) or the test substance at nominal concentrations of 0.32, 1.0, 3.2, 10, 32, or 100 mg/L. An additional replicate was exposed to a filtrate of a supersaturated stock suspension (100 mg/L) to determine the toxic effect of the dissolved part of the test item only. Analytical monitoring was not conducted as the laboratory was not able to establish a reproducible method to determine test item concentration. They tried Inductive Couples Plasma Emission Spectrometry (ICP-AES) and Atomic Absorption Spectroscopy (AAS) with a graphite furnace to detect the silicon. In the algal study below, Harlan laboratories used gas chromatography (GC) to detect the [REDACTED] without any problems.</p> <p>GC analysis might have been more appropriate for this new chemical submission. The 100 mg/L test solution was prepared by suspending 150 mg</p>

Test organism	Test Type	Test Endpoint	Predicted	Experimental Comments
		<p>of test item into 1.5 liters of water by intense stirring for 30 minutes and short ultrasonic treatment for 15 minutes. Adequate volumes were taken from the stirred test medium and were diluted with test water to prepare all other test concentrations. The filtrate of the supersaturated stock suspension was prepared by ultrasonically treating a 100 mg/L solution for 10 minutes, followed by stirring for 24 hours to dissolve the highest possible rate of test item. The stock suspension was then filtered through a cellulose nitrate filter (pore size 0.45 µm). No remarkable observations on test item behavior were noted at nominal concentrations ≤ 10 mg/L and in the filtrate. At nominal concentrations of 32 and 100 mg/L, a part of the test item was observed at the surface of the test water. Over the course of the study, temperature was maintained at 21°C, pH ranged from 7.3-7.9 and dissolved oxygen ranged from 7.9-8.7 mg/L. Dilution water hardness was 250 mg/L as CaCO₃. A loading rate of 66.7 daphnids/L was calculated. The % immobility at 0 (control), 0.32, 1.0, 3.2, 10, 32, and 100 mg/L was 0%, 0%, 10%, 0%, 35%, 100%, and 100%, respectively. The % immobility for the filtrate treatment was 80%. At 24 hours, all daphnids in the filtrate and 10 mg/L treatments were trapped at the water surface, but were not immobile; all daphnids in the 100 mg/L treatment were immobile. All surviving <i>Daphnia</i> were trapped at water surface at 24 hours in the 32 mg/L treatment and at 48 hours in the 10 mg/L treatment. Based on nominal concentrations, the 48-hour EC₅₀ was 12 mg/L. This is an acceptable test.</p> <p>48-hour EC₅₀ = 12 mg/L</p> <p>Algal Ecotoxicity Test: Harlan Laboratories Ltd. conducted a 72-hour acute toxicity test in green algae (<i>Pseudokirchneriella subcapitata</i>) with a monomer of the PMN [REDACTED]; [REDACTED] purity: 98.53%) under semi-static conditions with 24-hour renewal. The sponsor (Wacker Chemical Corporation) stated that, "It is reasonable to identify the monomer as a worst case structural surrogate for the notified polymer," P-18-0137. EPA agrees with this approach and notes that [REDACTED] hydrolyzes in approximately 40 hours to [REDACTED] and [REDACTED]. As a result, aquatic organisms will likely be exposed to [REDACTED] and its hydrolysis products during the test's exposure duration. The water solubility of the monomer ([REDACTED]) was reported to be < 0.25 mg/L. The water solubility of the hydrolysis products are 8.3 g/L (EpiSuite) for [REDACTED] and > 100 g/L (measured) for [REDACTED]. This study followed OECD test guideline No. 201 (2006), EU Commission Directive 92/69/EEC, C.3 (1992), and Commission Regulation (EC) No 440/2008, C.3. Following a range-finding test, three replicates</p>		

Test organism	Test Type	Test Endpoint	Predicted	Experimental Comments
				<p>of <i>P. subcapitata</i> (10,000 cells/mL) were exposed to a filtrate prepared at a loading rate of 100 mg test item/L as well as the following dilutions of the filtrate: 1:100, 1:32, 1:10, and 1:3.2. Additionally, six replicates were exposed to a blank control. At the start of the test, measured concentrations in the 1:3.2 dilution test media and the undiluted filtrate were 283 and 1189 µg/L, respectively, as determined by GC analysis (LOQ = 10.1 µg/L). At the end of the test, measured concentrations were below the LOQ. The algal cultures were illuminated with a light intensity of 7130-8240 lux, with continuous stirring. To prepare the dispersion with a loading rate of 100 mg/L, 150.15 mg of the test item was dispersed in 1500 mL of test water. The dispersion was supported by ultrasonic treatment for 15 minutes and intense stirring by a magnetic stirrer over 96 hours at room temperature in the dark, to dissolve a maximum amount of the test item. After the stirring period, the dispersion was allowed to settle for 15 minutes and was then filtered through a membrane filter (pore size 0.45µm). The negative pressure of the filtration unit was reduced as much as possible. The test water (containing the water-soluble part of the test item) was taken from the middle of the water column to avoid any undissolved test item in the test water. EPA determines that this approach mimics water accommodated fraction (WAF) testing. The undiluted filtrate was used as the highest concentrated test medium and as a stock solution for the preparation of the test media of lower test concentrations. For preparation of the test media of the lower concentrations, the filtrate was diluted with test water. Test media were prepared just before the start of exposure and all test media were clear solutions throughout the test. Over the course of the study, temperature ranged from 21-22°C and pH ranged from 8.1-8.2. Dilution water hardness was 24 mg/L as CaCO₃. The mean cell density of control cultures increased by a factor of 102 within 72 hours. No treatment-related effects on the appearance of algal cells were observed upon microscopic observation. Based on initial measured concentrations, the 72-hour EC₅₀ for growth rate and yield was greater than 1.2 mg/L. The 72-hour NOEC and LOEC for growth rate and yield, based on initial measured concentrations, were 0.283 mg/L and 1.189 mg/L, respectively. Even though these study methods mimic WAF testing without robust analytical monitoring, algae were likely exposed to the two hydrolysis products due to their high water solubility values. As a result, this study is acceptable for risk assessment purposes.</p> <p>72-hour EC₅₀ (growth rate and yield) > 1.189 mg/L 72-hour NOEC (growth rate and yield) 0.283 mg/L 72-hour LOEC (growth rate and yield) 1.189 mg/L</p>

Test organism	Test Type	Test Endpoint	Predicted	Experimental	Comments
		Algal ChV = 0.58 mg/L			
		Conclusions			
		Wacker Chemical Corporation, the sponsor, submitted three acceptable ecotoxicity studies (fish, daphnid, and algae) on the “worst case structural surrogate (per the sponsor)” for the notified polymer, P-18-0137. From the submitted ecotoxicity studies, the acute ecotoxicity endpoint values for fish, aquatic invertebrates, and algae are 41 mg/L, 12 mg/L, and > 1.189 mg/L, respectively. Furthermore, the chronic endpoint value (chronic value [ChV]) for algae, from the submitted study, is 0.58 mg/L, based on the initial (t=0) measured values for the NOEC and LOEC. Since chronic fish and chronic aquatic invertebrate studies were not submitted by the sponsor and acceptable acute studies were submitted with adverse effects, the chronic values for the fish and aquatic invertebrate are 4.1 mg/L and 1.2 mg/L, respectively, based on an acute to chronic ratios of 10 for both endpoints. Based on ECOSAR (v. 2.0), the predicted acute ecotoxicity endpoint values for fish, aquatic invertebrates, and algae for P-18-0137 are > 100, 75.1, 57.9 mg/L, respectively. Based on ECOSAR (v. 2.0), the predicted chronic values for fish, aquatic invertebrates, and algae for P-18-0137 are 12.9, 7.5, 15.4 mg/L, respectively. Based on the submitted acute aquatic invertebrate toxicity study (48-hr EC50), the acute concentration of concern (COC) is 2.4 mg/L (aquatic invertebrate 48-hr EC50 / assessment factor of 5). The chronic COC is 0.058 mg/L (Algal ChV / assessment factor of 10), based on the submitted algal toxicity study.			
		Acute COC = 2.4 mg/L or 2,400 µg/L			
		Chronic COC = 0.058 mg/L or 58 µg/L			
		Ecotox Reviewer: J. Gallagher			
		Date:			
		April 19, 2018			

Ecotox Factors

Factors	Most Sensitive Endpoint	Assessment Factor	CoC	Comment
Acute Aquatic (ppb):	12000	5	2400	48-hr Dm EC50 (measured)
	580	10	58	

Factors	Most Sensitive Endpoint	Assessment Factor	CoC	Comment
Chronic Aquatic(ppb):				Algal ChV (measured)
Factors	Values	Comments		
SARs: SAR Class: TSCA NCC Category?	Neutral Organics			

Recommended**Testing:****Ecotox Factors Focus****Comments:** Report/Decision Document:

Environmental Hazard and Risk
(P-18-0137)

Environmental Hazard: Environmental hazard is relevant to whether a new chemical substance is likely to present unreasonable risks because the significance of the risk is dependent upon both the hazard (or toxicity) of the chemical substance and the extent of exposure to the substance. EPA estimated environmental hazard of this new chemical substance using hazard data for the new chemical substance. Based on these hazard values for the new chemical substance, EPA concludes that this chemical substance has moderate environmental hazard.

- Substance falls within the TSCA New Chemicals Category of neutral organics (low molecular weight).
- Acceptable acute fish, acute aquatic invertebrate and algal toxicity test data was submitted on P-18-0137.
- Based on submitted acute toxicity test data on the PMN, the acute toxicity values for fish, aquatic invertebrates and algae are 41 mg/L, 12 mg/L, and > 1.189 mg/L, respectively.
- Based on submitted chronic toxicity test data on the PMN (with the application of an acute to chronic ratio assessment factor of 10 for fish and aquatic invertebrates), the chronic toxicity values are 4.1 mg/L, 1.2 mg/L, and 0.58 mg/L, respectively, for fish, aquatic invertebrates, and algae.
- These toxicity values indicate that the new chemical substance is expected to

have moderate environmental hazard.

- Application of assessment factors of 5 and 10 to acute and chronic toxicity values, respectively, results in acute and chronic concentrations of concern of 2.4 mg/L (2400 ppb; aquatic invertebrate EC50 acute toxicity value [submitted test data on PMN]) and 0.058 mg/L (58 ppb; algal chronic toxicity value [submitted test data on the PMN]), respectively.

Environmental Risk:

Risks to the environment were evaluated by comparing estimated surface water concentrations with the acute and chronic concentrations of concern. Acute risks to the environment were not identified for this PMN since the acute COC of 2400 ppb was not exceeded (surface water concentration [SWC]: 29.1 ppb) during the use scenario. Chronic risks to the environment were not identified for this PMN since the chronic COC of 58 ppb was not exceeded (SWC: 21.9 ppb) during the use scenario.

Comments/Telephone Log

Artifact	Update/Upload Time
[REDACTED]	[REDACTED]